Patent 17510DIV1 (BOT) 19 57205-00112

Appl. No.: 10/675,020

Art Unit: 1645

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

- 1-15. (Cancelled)
- 16. (Previously Presented) A transdermal patch, comprising;
 - a) a pharmaceutical composition comprising
 - i) a stabilized botulinum toxin provided in a dried state; and
 - ii) an enhancing agent that is mixable with the stabilized botulinum toxin provided in a dried state and facilitates transdermal administration of a botulinum toxin in a bioactive form to a subdermal target site of a human patient without being administered to the patient's circulatory system; and
 - an adhesive layer disposed to one side of the transdermal patch to removably secure the patch on the patient's skin;
 - wherein the pharmaceutical composition is incorporated into the adhesive layer; and
 - wherein upon contacting with a fluid, the fluid solubilizes the pharmaceutical composition, thereby permitting diffusion of the pharmaceutical composition from the adhesive layer.
- (Previously Presented) The transdermal patch of claim 16, wherein the adhesive layer is disposed around a depot containing the pharmaceutical composition.

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18. (Original) The transdermal patch of claim 16, further comprising a plurality of needles extending from one side of the patch that is applied to the skin, wherein the needles extend from the patch to project through the stratum corneum of the skin without rupturing a blood vessel.

- 19. (Original) The transdermal patch of claim 18, wherein the botulinum toxin is provided a depot in a patch so that pressure applied to the patch causes botulinum toxin to be directed through the needles and under the stratum corneum.
- 20. (Previously Presented) A transdermal patch comprising:
 - a) a depot comprising a plurality of wells covered by a membrane, the wells containing a pharmaceutical composition comprising
 - i) a stabilized botulinum toxin provided in a dried state; and
 - an enhancing agent that is mixable with the stabilized botulinum toxin provided in a dried state ad facilitates transdermal administration of a botulinum toxin in a bioactive from to a subdermal target site of a human patient without being administered to the patient's circulatory system; and
 - an adhesive layer disposed to one side of the transdermal patch to removably secure the patch on the patient's skin;
 - wherein upon contacting with a fluid, the membrane covering the wells dissolves and the fluid solubilizes the pharmaceutical composition, thereby permitting diffusion of the pharmaceutical composition from the well.
- (Original) The transdermal patch of claim 16, wherein the botulinum toxin is botulinum toxin type A.

22-35. (Cancelled)

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36. (Previously Presented) The transdermal patch of claim 16, wherein the enhancing agent comprises 1 part water, 1 part ethanol, and 1 part polyethylene glycol.

- 37. (Currently Amended) The trasdermal transdermal patch of claim 36 wherein the ethanol is 90% ethanol.
- 38. (Previously Presented) The transdermal patch of claim 16, wherein the enhancing agent comprises 1 part of 10% transfersomes and 0.9 part of a buffer.
- 39. (Previously Presented) A transdermal patch, comprising:
 - a) a pharmaceutical composition comprising
 - a stabilized botulinum toxin provided in a dried state; and
 - ii) an enhancing agent that is mixable wit the stabilized botulinum toxin provided in a dried state and facilitates transdermal administration of the botulinum toxin in a bioactive form to a subdermal target site of a human patient; and
 - an adhesive layer disposed on one side of the transdermal patch to removably secure the patch on the patient's skin.
 - wherein the pharmaceutical composition is incorporated into the adhesive laver; and
 - wherein upon contacting with a fluid, the fluid solubilizes the pharmaceutical composition, thereby permitting diffusion of the pharmaceutical composition from the adhesive layer.
- 40 (Previously Presented) The transdermal patch of claim 39, wherein les than 25% of the administered botulinum toxin permeates into a blood vessel.

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41. (Previously Presented) The transdermal patch of claim 39, wherein the enhancing agent comprises 1 part water, 1 part ethanol, and 1 part polyethylene glycol.

- 42. The transdermal patch of claim 39 wherein the (Previously Presented) ethanol is 90% ethanol.
- 43. (Previously Presented) The transdermal patch of claim 39, wherein the enhancing agent comprises 1 part of 10% transfersomes and 0.9 part of a buffer.
- 44. (Previously Presented) The transdermal patch of claim 39, wherein the botulinum toxin is botulinum toxin type A.
- 45. (Previously Presented) The transdermal patch of claim 20, wherein the botulinum toxin is botulinum toxin type A.